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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,702

09/07/2004

Michael J Breslin

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EXAMINER

HAVLIN, ROBERT H

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

12/10/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/506,702	<b>Applicant(s)</b> BRESLIN ET AL.	
	<b>Examiner</b> ROBERT HAVLIN	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 6 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6 and 10 is/are rejected.
- 7) ☒ Claim(s) 6 and 8-10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/6/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

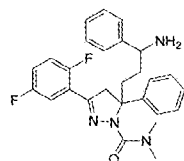
### DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/16/08 has been entered.

**Status of the claims:** Claims 6 and 8-10 are currently pending. Claims 3, and 4 were cancelled.

**Restriction/Election:** Applicant previously elected group I and the following species:

5-(3-amino-3-phenylpropyl)-3-(2,5-difluorophenyl)-N,N-dimethyl-5-phenyl-4,5-dihydro-1H-pyrazole-1-carboxamide



for examination. The scope of examination

was expanded beyond the elected species within the scope of claim 6 and art was found rendering the claim obvious. Because the generic claim encompassing the elected species was found unpatentable (as detailed in the new rejection below), the scope of the claims examined remains restricted to the elected species only.

### RESPONSE TO APPLICANT REMARKS

#### *Claim Rejections - 35 USC § 102*

1. Claims 3, 4, and 10 were rejected under 35 U.S.C. 102(b) as being anticipated by Pavagadhi et al. (CAPLUS Abstract of Pavagadhi et al., Journal of the Institution of

Chemists (India) (2001), 73(3), 97-98. Accession # 2002:199098.). This rejection is **withdrawn** based on the claim amendments.

2. Claims 3, 4, and 10 were rejected under 35 U.S.C. 102(b) as being anticipated by Joshi et al. (CAPLUS Abstract of Joshi et al., Journal of the Indian Chemical Society (1984), 61(11-12), 1014-15. Accession # 1986:34035.). This rejection is **withdrawn** based on the claim amendments.

#### ***Claim Rejections - 35 USC § 112***

3. Claims 3, 4, 8, and 10 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This rejection is **withdrawn** because of the claim amendments deleting the objectionable language.

#### ***Claim Objections***

4. Claims 8, and 10 were objected to as being dependent on a rejected base claim. Claims 6, 8-10 were objected to for reading on non-elected subject matter in view of the restriction to the scope of the elected species. **These objections are maintained** because of the following new rejections.

#### **NEW CLAIM REJECTIONS**

#### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

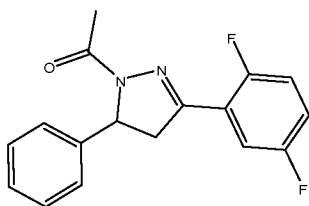
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6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joshi et al. (CAPLUS Abstract of Joshi et al., Journal of the Indian Chemical Society (1984), 61(11-12), 1014-15. Accession # 1986:34035.) in view of Silverman, R. B. (The Org. Chem. of Drug Design and Drug Action, Academic Press, Inc.: San Diego, 1992, pp. 4-51).

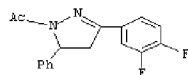
The claims include the compound (listed in claim 6):



1-Acetyl-3-(2,5-difluorophenyl)-5-phenyl-4,5-dihydro-1H-pyrazole

Determining the scope and contents of the prior art

Joshi et al. teaches the following compound:



as a pharmaceutical agent.

Silverman teaches drug discovery, design, and development through modifications of the structure of known molecules showing some activity. For example, Silverman teaches on page 23 the methodology of QSAR. Specifically, the method teaches altering the position of halogen substituents alters pharmacological efficacy.

Ascertaining the differences between the prior art and the claims at issue

The difference between the Joshi compound and the claims is moving the 2-fluoro substituent to the 4-position.

Resolving the level of ordinary skill in the pertinent art.

One of ordinary skill in the art of pharmaceutical development would be well versed in the teachings of references such as Silverman. One of ordinary skill in the art would consider routine and well within their technical grasp the process of altering the substituents on drug molecules and screen them for activity on a large scale to improve potency.

Considering objective evidence present in the application indicating obviousness

Upon reading the teachings of Joshi, one of ordinary skill in the art would immediately recognize potential to improve the potency of the compounds taught therein through altering the substituents via homologation and QSAR. Silverman specifically teaches the QSAR methodology and provides the underlying physicochemical motivation of altering the lipophilicity, stereocompatibility, electronics, etc. of the molecule which would reasonably be applicable to the compound of Joshi. In addition, the Joshi compound is a positional isomer of the instant claims, only differing

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by the location of a group, thus one of ordinary skill in the art would expect the physical properties of the two compounds to be similar.

This is further supported by caselaw and the MPEP in section 2144.09(II):

Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH<sub>2</sub>- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977); see also In re May, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978).

Therefore, because the reference teaches positional isomers of the instantly claimed compounds and the MPEP states that positional isomers are presumed to possess similar properties, it would have been obvious to one of ordinary skill in the art to modify the position of the substituent and arrive at the instant invention.

One of ordinary skill in the art would have been guided by the prior art to make the invention as claimed because Joshi teaches the homologous/isomeric compound, while Silverman teach how to modify the compound to arrive at the instant invention. Therefore, the claims are obvious.

### ***Conclusion***

No claims are in condition for allowance. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is

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(571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/  
Examiner  
Art Unit 1626

/Kamal A Saeed, Ph.D./  
Primary Examiner, Art Unit 1626